

REMARKS

Applicants have amended the claims to address the 35 U.S.C. § 112, ¶ rejections made by the Examiner. Applicants have further defined the catalytic role of UDP-glucouronoyltransferase and sulfotransferase, as that role applies to hair growth. Support for the amendments can be found on page 2 of the specification. Applicants also have provided the full name for UDP in the claims, and on page 2 of the specification; a person of ordinary skill in the art would know that UDP stands for uridine diphosphate, and as a result, the amendment does not add new matter.

Claims 1, 2, 18, and 20-38 were rejected under 35 U.S.C. § 112, ¶ 1. The Examiner has focused on CA 125:293042. This is an abstract of a published PCT application that corresponds to pending application U.S.S.N. <sup>963 227</sup>~~950,228~~. A full copy of the application is enclosed for the convenience of the Examiner.

Applicants agree that CA 125:293042 teaches that topical application of an inhibitor of sulfotransferase will reduce hair growth. But there are many different sulfotransferases in the body. Persons of ordinary skill in the art would understand that the sulfotransferase described in CA 125:293042 are involved in angiogenesis. In contrast, the sulfotransferase in question in the present application acts on androgens involved in hair growth. These are different pathways, and what happens when a sulfotransferase involved in angiogenesis is inhibited has no bearing on the enablement of the methods

claimed in the present application. Applicants have amended claims 1, 2, 17, and 18 to better define the catalytic role of the sulfotransferase.

Although it appears that CA 125:293042 was the major 35 U.S.C. § 112, ¶ 1 concern of the Examiner, applicants nevertheless will explain why the specification of the present application satisfies the requirement of 35 U.S.C. § 112, ¶ 1.

As explained by the Board of Appeals in Ex parte Forman, 230 U.S.P.Q. 546, 547 (1986), 35 U.S.C. § 112, ¶ 1 requires applicants to provide a sufficient disclosure

to enable one having ordinary skill in the relevant field to practice the invention claimed therein without the exercise of undue experimentation.

The Board went on to explain the factors that are considered in deciding when experimentation becomes "undue" (id.):

The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art: Ansul Co. v. Uniroyal, Inc. [169 U.S.P.Q. 759, 762 (2d Cir. 1971)].

\* \* \*

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. In re Rainer, 52 CCPA 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965); In re Colianni, *supra*.

The invention in its broadest sense is the recognition that hair growth can be modulated by topical application of a compound that induces or activates the conjugation of an androgen involved in hair growth to form a conjugate that can be more readily eliminated from the site of action in the body, or is less active than the parent androgen. As explained in the specification, the effect on hair growth will be dependent on the type of hair growth involved.

A person skilled in the art, reading applicants specification, would be able to practice this invention broadly without undue experimentation. Therefore, the applicants have met the requirements of 35 U.S.C. § 112, ¶ 1. Applicants will apply each of the factors mentioned in Forman to the current facts, and explain why the facts demonstrate that the broad invention (and its narrower aspects) can be practiced without undue experimentation. Applicants will begin with a key factor, the nature of the invention.

#### **1. Nature of the invention**

What is meant by "the nature of the invention" was discussed in the Ansul decision cited by the Board in Forman. In Ansul the Court explained that inventors who discover "a new use for existing composition" are entitled to broad, generic claims even if the inventors have not disclosed every potential embodiment of the invention (see 169 U.S.P.Q. at 762).

What this means in the context of the present invention is that applicants are not required to disclose and test every compound that induces or activates the conjugation of an androgen

involved in hair growth in order to be entitled to a generic patent. Their invention is not the compounds. Rather, like in Ansul, applicants discovered a new use (modulating hair growth) for classes of compounds that are known.

Amending the claims to cover only the use of compounds that applicants have named and tested would allow competitors after reviewing the patent to use other compounds that induce or activate the conjugation of an androgen involved in hair growth to modulate hair growth in order to avoid literally falling within the claims while still taking advantage of applicants' contribution. This result would be unfair to applicants. The Court of Customs and Patent Appeals, in In re Goffe, 191 U.S.P.Q. 429, 431 (1976), explained why:

For all practical purposes the board would limit appellant to claims involving the specific materials disclosed in the examples, so that a competitor seeking to avoid infringing the claims would merely have to follow the disclosure in the subsequently-issued patent to find a substitute. However, to provide effective incentive, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

## **2. Quantity of experimentation necessary**

A person skilled in the art would have to conduct little experimentation to practice the invention broadly. Applicants discussed a number of general ways to induce or activate an androgen involved in hair growth, and identified at

least 14 compounds that can be used, along with suitable vehicles and protocols. A person skilled in the art, looking to find additional compounds, simply could do what applicants did-- search the literature to find additional compounds that have the desired activity.

Moreover, to the extent there is doubt that a particular compound would modulate hair growth, the specification provides a very straight-forward test that can be used to identify easily those compounds (if any) that do not work. Cf. In re Wands, 8 U.S.P.Q.2d 1400, 1404-06 (Fed. Cir. 1988) (finding no undue experimentation where specification provided screening test).

The lack of experimentation necessary to practice the invention further brings out why applicants are entitled to broad protection. The Court in Ansul described how easy it is under these circumstances for others to appropriate an inventor's contribution (169 U.S.P.Q. at 762, quoting district court):

With astonishing rapidity [the infringers] used the new discovery and teachings in routine experiments, featuring routine screening techniques, to develop practical uses for the product. None of this would have occurred, of course, if it had not been for Uniroyal's disclosure of the basic secret with sufficient information for researchers to use the compound in their regular sampling procedures.

**3. The presence or  
absence of working examples**

Applicants provided 7 working examples (see Table 1). Courts in analogous situations have found the quantity of testing to be adequate. For example, in In re Boller, 141 U.S.P.Q. 740

(C.C.P.A. 1964), the claimed invention was using volatile neutralizing agents in a chemical process. The patent specification described only a limited number of neutralizing agents that could be used in the process. The court, focusing on the claimed invention rather than on the absence of examples of other neutralizing agents that could be used in the process, held that the claim was broadly enabled:

This is a broad invention and, as noted by the board, appellant is entitled to claims commensurate with the disclosure. Accordingly, we believe that appellant's disclosure, even though of a limited class of "volatile neutralizing agents," is sufficient to justify claims which define broadly a volatile neutralizing agent. Use of this term is commensurate with the breadth of the invention as disclosed. We think any chemist skilled in this art is fully apprised by appellant's disclosure of what the invention is and is taught how to use it. Appellant need not disclose every operative "volatile neutralizing agent."

Id. at 743 (citation omitted).

#### **4. The state of the prior art**

The prior art does not teach a connection between inducing or activating the conjugation of an androgen involved in hair growth and modulating hair growth. The invention thus is of pioneer status, and entitled to broad protection. As the court commented in In re Hogan, 194 U.S.P.Q. 527, 537 (C.C.P.A. 1977) (emphasis added):

[W]e note appellants' argument that their invention is of "pioneer" status. The record reflects no citation of prior art disclosing a solid polymer of 4-methyl-1-pentene, which may suggest that appellants at least broke new ground in a broad sense. On remand,

appellants may be found to have been in fact the first to conceive and reduce to practice "a solid polymer" as set forth in claim 13. As pioneers, if such they be, they would deserve broad claims to the broad concept.

**5. The predictability of the art**

The chemical/biochemical arts generally are unpredictable. This also applies to the state of the hair growth art when applicants made their invention. Nobody knew that topical application of compounds that induce or activate the conjugation of an androgen involved in hair growth actually could be used to modulate hair growth until applicants conducted their research. But now that applicants have conducted their work, it is predictable that such compounds applied topically in an appropriate vehicle will work to modulate hair growth.

**6. Breadth of the claims**

The claims cover no more than applicants' contribution.

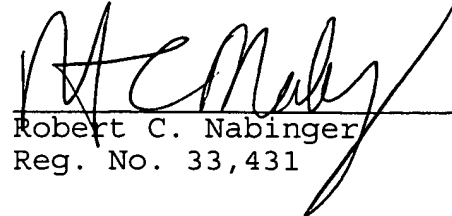
**CONCLUSION**

Applicants submit that the claims are now in condition for allowance, and action is requested. Filed herewith is a Petition for Automatic Extension with the required fee.

Please charge any additional fees, or make any credits,  
to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 2/12/99

  
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